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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,752	10/19/2001	Reinhold Schmieding	P/1493-443	6145
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DICKSTEIN SHAPIRO LLP 1825 EYE STREET NW Washington, DC 20006-5403			EXAMINER NAJARIAN, LENA	
			ART UNIT 3626	PAPER NUMBER
			MAIL DATE 12/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/981,752		SCHMIEDING, REINHOLD	
	<b>Examiner</b>		<b>Art Unit</b>	
	Lena Najarian		3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Notice to Applicant***

1. This communication is in response to the Request for Continued Examination (RCE) filed 10/23/07. Claims 1, 3, 8, 9, 14, and 15 have been amended. Claim 16 has been canceled. Claims 1-15 and 17 remain pending.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), and further in view of Applicant's admitted prior art (admission) given in "Brief Description of the Related Art" section of application.

(A) Referring to claim 1, Bradbury discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (para. 64 of Bradbury):

providing predetermined specifications and conditions of a patient from a medical provider to a service provider (Fig. 2, para. 7, and para. 15 of Bradbury);

subsequently customizing an allograft to be used in a predetermined surgical procedure, the allograft being customized to the predetermined specifications and

conditions of the patient and of the predetermined surgical procedure to be performed on the patient (para. 8 of Bradbury); and

coordinating, by the service provider, delivery of the customized allograft to the medical provider (para. 15 of Bradbury).

Bradbury does not expressly teach that the customizing is done *at a tissue bank*. Bradbury does disclose providing, by the service provider, graft specific surgical instrumentation to match the specifications of the allograft and the procedure (para. 28 of Bradbury). However, Bradbury does not disclose *loaning* the instrumentation.

Filho discloses receiving the implant from a tissue bank (col. 3, lines 46-53 and col. 4, lines 20-22 of Filho).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Filho within Bradbury. The motivation for doing so would have been to provide an appropriate place for the storage of the implants (col. 3, lines 46-53 of Filho).

Admission discloses loaning the surgical instrumentation (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of loaning surgical instrumentation with the motivation of providing for a specified time period the appropriate instruments if the surgeon or medical facility does not already own the necessary instrumentation (p. 1, lines 12-19 of Specification).

(B) Referring to claim 2, Bradbury discloses coordinating delivery of the allograft to a medical facility at which the surgical procedure is to be performed with delivery of the surgical instrumentation (para. 15 and para. 28 of Bradbury).

(C) Referring to claim 3, Bradbury discloses wherein the allograft is delivered directly to the medical facility (para. 15 of Bradbury).

Bradbury does not expressly disclose wherein the allograft is harvested at the tissue bank.

Filho discloses wherein the allograft is harvested at the tissue bank (col. 3, lines 46-53 of Filho).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Filho within Bradbury. The motivation for doing so would have been to keep the implant in proper storage for later use (col. 3, lines 46-53 of Filho).

(D) Referring to claim 4, Bradbury and Filho do not disclose training operating personnel in the use of the instruments and skills to perform the surgical procedure.

Admission discloses training operating personnel in the use of the instruments and skills to perform the surgical procedure (page 1, line 19 - page 2, line 1 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of training operating personnel with the motivation of

the surgeon being informed if he or she is unfamiliar with the procedure or needs a refresher course (page 1, lines 19-21 of Specification).

(E) Referring to claim 8, Bradbury discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (para. 64 of Bradbury):

providing predetermined specifications and conditions of a patient from a medical provider to a service provider (Fig. 2, para. 7, and para. 15 of Bradbury);

arranging, by the service provider, for delivery of a customized allograft for a predetermined surgical procedure, the customized allograft being sized according to the specifications and conditions of the patient and of the predetermined surgical procedure (para. 8 and para. 15 of Bradbury);

customizing, by the service provider, a surgical instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure (para. 28 of Bradbury), and

providing, by the service provider, the customized surgical instrumentation kit to the medical provider for the performance of the surgical procedure (para. 28 of Bradbury).

Bradbury does not expressly disclose that the allograft is sized by a tissue bank and that the service provider loans the surgical instrumentation.

Filho discloses receiving the implant from a tissue bank (col. 3, lines 46-53 and col. 4, lines 20-22 of Filho).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Filho within Bradbury. The motivation for doing so would have been to provide an appropriate place for the storage of the implants (col. 3, lines 46-53 of Filho).

Admission discloses loaning the surgical instrumentation (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of loaning surgical instrumentation with the motivation of providing, for a specific amount of time, the appropriate instruments if the surgeon or medical facility does not already own the necessary instrumentation (p. 1, lines 12-19 of Specification).

(F) Referring to claim 9, Bradbury discloses wherein the allograft is delivered directly to a medical facility at which the surgical procedure is to be performed (para. 15 of Bradbury).

Bradbury does not expressly disclose wherein the allograft is harvested at the tissue bank.

Filho discloses wherein the allograft is harvested at the tissue bank (col. 3, lines 46-53 of Filho).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Filho within Bradbury. The

motivation for doing so would have been to keep the implant in proper storage for later use (col. 3, lines 46-53 of Filho).

(G) Referring to claim 10, Bradbury and Filho do not disclose prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure.

Admission discloses prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure (page 1, line 19 – page 2, line 1 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of training operating personnel with the motivation of the surgeon being informed if he or she is unfamiliar with the procedure or needs a refresher course (page 1, lines 19-21 of Specification).

4. Claims 5-6 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), in view of Applicant's admitted prior art (admission) given in "Brief Description of the Related Art" section of application, and further in view of Ramshaw et al. (5,791,907).

(A) Referring to claim 5, Bradbury, Filho, and Admission do not expressly disclose providing technical support during the procedure.

Ramshaw discloses providing technical support during the procedure (col. 1, lines 12-24 and 49-65 of Ramshaw).



At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Bradbury, Filho and Admission. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

(B) Referring to claim 6, Bradbury, Filho, and Admission do not expressly disclose wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments and the performance of the surgical procedure at an operation location during the procedure.

Ramshaw discloses wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments and the performance of the surgical procedure at an operation location during the procedure (col. 1, lines 12-24 and 49-65 and col. 15, lines 13-17 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Bradbury, Filho and Admission. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user and notify him/her of incorrect choices (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

(C) Referring to claim 11, Bradbury, Filho, and Admission do not disclose providing technical support to operating personnel before and/or during the performance of the procedure.

Ramshaw discloses providing technical support to operating personnel before and/or during the performance of the procedure (col. 1, lines 12-24 and 49-65 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Bradbury, Filho, and Admission. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

(D) Referring to claim 12, Bradbury, Filho, and Admission do not expressly disclose wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure.

Ramshaw discloses wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure (col. 1, lines 12-24 and 49-65 and col. 15, lines 13-17 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Bradbury, Filho, and Admission. The motivation for doing so would have been to have a qualified

instructor or proctor present to instruct the user and notify him/her of incorrect choices (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

5. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), in view of Applicant's admitted prior art (admission) given in "Brief Description of the Related Art" section of application, and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning").

(A) Referring to claim 7, Bradbury, Filho and Admission do not expressly disclose arranging for the return of the surgical instrumentation after performance of the procedure.

AORN discloses arranging for the return of the surgical instrumentation after performance of the procedure (p. 1062-1063 of AORN).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of AORN within Bradbury, Filho and Admission. The motivation for doing so would have been to return the borrowed instruments to the outside party (p. 1062 of AORN).

(B) Referring to claim 13, Bradbury, Filho, and Admission do not expressly disclose arranging for the return of the customized surgical instrumentation kit after performance of the surgical procedure.

AORN discloses arranging for the return of the surgical instrumentation after performance of the procedure (p. 1062-1063 of AORN).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of AORN within Bradbury, Filho, and Admission. The motivation for doing so would have been to return the borrowed instruments to the outside party (p. 1062 of AORN).

6. Claims 14, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), and further in view of Ramshaw et al. (5,791,907).

(A) Referring to claim 14, Bradbury discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (para. 64 of Bradbury):

providing predetermined specifications and conditions of a patient from a medical provider to a service provider (Fig. 2, para. 7, and para. 15 of Bradbury);

customizing and sizing an allograft according to the specifications and conditions of the patient and of a predetermined surgical procedure (para. 8 of Bradbury);

arranging, by the service provider, for delivery of the customized allograft for the predetermined surgical procedure to a medical facility at which the predetermined surgical procedure is to be performed (para. 15 of Bradbury);

Bradbury does not expressly disclose that the customizing and sizing of an allograft is done at a *tissue bank*.

Filho discloses receiving the implant from a tissue bank (col. 3, lines 46-53 and col. 4, lines 20-22 of Filho).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Filho within Bradbury. The motivation for doing so would have been to provide an appropriate place for the storage of the implants (col. 3, lines 46-53 of Filho).

While Bradbury does disclose providing customer support (see para. 63-64 of Bradbury), Bradbury and Filho do not expressly disclose providing, by the service provider, technical support and/or customer support to operating personnel before and/or during performance of the predetermined surgical procedure at the medical facility; and prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure.

Ramshaw discloses providing, by the service provider, technical support and/or customer support to operating personnel before and/or during the performance of the predetermined surgical procedure at the medical facility (col. 2, lines 39-56 and col. 1, lines 12-24 of Ramshaw) and prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure (abstract and col. 10, lines 32-61 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Bradbury and Filho. The motivation for doing so would have been to ensure the proper and safe performance of the surgical procedures (col. 1, lines 43-48 of Ramshaw).

(B) Referring to claim 15, Bradbury discloses wherein the allograft is delivered directly to a medical facility at which the surgical procedure is to be performed (para. 15 of Bradbury).

Bradbury does not expressly disclose wherein the allograft is harvested at the tissue bank.

Filho discloses wherein the allograft is harvested at the tissue bank (col. 3, lines 46-53 of Filho).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Filho within Bradbury. The motivation for doing so would have been to keep the implant in the proper storage for later use (col. 3, lines 46-53 of Filho).

(C) Referring to claim 17, Bradbury and Filho do not expressly disclose wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure.

Ramshaw discloses wherein the step of providing technical support includes providing for the presence of a trained representative knowledgeable in the use of the instruments in the instrumentation kit and in the performance of the surgical procedure at an operation location during the procedure (col. 1, lines 12-24 and 49-65 and col. 15, lines 13-17 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Bradbury and Filho. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user and notify him/her of incorrect choices (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 1-15 and 17 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***


8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a method and apparatus for osteochondral autograft transplantation (5,919,196); and method for

preparing and inserting round, size specific osteochondral cores in the knee (US 6,591,581 B2).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
In  
12-12-07

  
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